

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL No. 2327
THIS DOCUMENT RELATES TO ETHICON WAVE 3 CASES	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

**MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE THE
TESTIMONY OF KIMBERLY KENTON, M.D.¹**

Dr. Kenton is a board-certified urogynecologist, internationally recognized as a leader in Female Pelvic Medicine & Reconstructive Surgery/Urogynecology. She has extensive experience as a surgeon, educator, and researcher in her field. She is a member of and has held leadership positions in many major professional associations. Dr. Kenton has performed a variety of procedures including Burch, bladder neck fascial slings, and synthetic mesh slings. She has performed over 1,000 TVT and TVT Exact and 250 TVT-O procedures. Her extensive experience in the field as a surgeon, educator, and researcher resulted in her leadership in national certifying and credentialing organizations. She has also worked extensively participating in and designing trials, including the largest US comparative effectiveness trial comparing Monarc and TVT-O transobturator midurethral slings to the gold standard TVT retropubic midurethral sling manufactured by Ethicon (“TOMUS Study”).

Despite Dr. Kenton’s extensive qualifications, Plaintiffs seek to exclude her opinions about (1) mesh properties, (2) the differences, or lack thereof, between mechanical- and laser-cut

¹ This response applies to those Wave 3 cases identified in Exhibit A to Plaintiffs’ Notice of Adoption, Dkt. 2800.

TVT devices, (3) complications, and (4) the Blaivas article, as well as her opinions which Plaintiffs allege contradict her deposition testimony.² On August 31, 2016, the Court entered an order denying Plaintiffs' motion in part, granting in part, and reserving in part. *See In re: Ethicon, Inc.* ("Order"), No. 2327, 2016 WL 4945099 (S.D. W. Va. Aug. 31, 2016). Ethicon requests that the Court adopt its rulings denying Plaintiffs' motion as to opinions on mesh properties, Dr. Kenton's qualifications to offer opinions on the lack of differences between mechanical and laser-cut mesh, the Blaivas article, and Dr. Kenton's deposition testimony. As to the Court's rulings on the reliability of Dr. Kenton's opinions regarding mechanical and laser-cut mesh and her opinions on complications, Ethicon requests that the Court consider the additional arguments below and deny Plaintiffs' motion to exclude Dr. Kenton's testimony on these topics.

ARGUMENTS AND AUTHORITIES

I. Dr. Kenton Is Qualified to Offer Opinions on the Properties of Mesh.

As the Court stated in its Order, Plaintiffs "challenge Dr. Kenton's qualifications to opine on the chemical, structural, or biomechanical makeup of the TVT device because she lacks training in 'chemical or structural engineering and/or in biomechanics.'" *In re: Ethicon*, 2016 WL 4945099, at *3. The Court rejected this contention, noting that, Dr. Kenton's "extensive clinical and research experience, combined with [her] review of clinical literature, qualifies Dr. Kenton to opine on mesh's reaction to and effect on the human body, and relatedly, the safety and efficacy of mesh products." *Id.* Plaintiffs have adopted their Wave 1 motion and

² Plaintiffs have incorporated by reference their *Daubert* challenge to Dr. Kenton's opinions filed in Wave 1. Pltfs. Notice of Adoption (Dkt. 2800) (incorporating Plaintiff's Wave 1 Kenton motion and memorandum, Dkts. 2087 and 2088, respectively). In response, Ethicon incorporates by reference its Opposition to Plaintiffs' Wave 1 motion ("Wave 1 Opposition") (Dkt. 2132) and Opposition to Plaintiffs' Wave 2 motion ("Wave 2 Opposition") (Dkt. 3536), which adopts and incorporates its Wave 1 Opposition except that it modifies section A.2 of its Wave 1 Opposition.

memorandum without modification, and Ethicon has incorporated by reference its Wave 1 Opposition. *See supra* n.1. As nothing has changed with respect to this argument, Ethicon requests that the Court adopt its Wave 1 ruling here.

II. Dr. Kenton has the Necessary Qualifications and Experience to Opine on the Lack of Clinical Differences between Mechanical- and Laser-Cut Mesh.

The Court also rejected Plaintiffs' argument that Dr. Kenton is "not qualified to offer expert testimony on whether there are clinical differences between mechanical-cut and laser-cut mesh products," noting that "a urogynecologist who has extensive experience working with mechanical-cut and laser-cut mesh products – like Dr. Kenton – is qualified to offer expert testimony of this sort." *Id.* at *2. Again, as Plaintiffs have adopted their Wave 1 argument without modification and Ethicon has incorporated its argument in opposition, Ethicon requests that the Court adopt its Wave 1 ruling here.

III. Dr. Kenton's Opinions on Mechanical- and Laser-Cut Mesh are Reliable.

The Court reserved ruling on the reliability of Dr. Kenton's opinions about mechanical-cut and laser-cut mesh on the grounds that her opinions are based primarily on her clinical experiences. *Id.* at *3. In its Wave 2 Opposition, incorporated herein, Ethicon explained further the bases for Dr. Kenton's opinion, providing additional citations to her Report and testimony. For the reasons set forth in both its Wave 1 and Wave 2 Oppositions, Ethicon respectfully asserts that the Court need not reserve ruling on this issue and requests that the Court deny Plaintiff's motion to exclude Dr. Kenton's opinions on mechanical-cut and laser-cut mesh.

IV. Dr. Kenton's Opinions on Chronic Pain are Reliable.

The Court also reserved ruling on "the reliability of Dr. Kenton's opinions regarding the rarity of post-operative chronic pain, because Dr. Kenton does not explain why she relies on certain studies for some purposes but not for chronic pain opinions." *Id.* at *3. As noted by the

Court, the Plaintiffs “challenge Dr. Kenton’s opinions on the basis that she failed to consider other existing scholarship regarding “episodes” of chronic pain.” *Id.* In addition to the bases for her opinions outlined in its Wave 1 Opposition, Ethicon now offers further explanation Dr. Kenton’s opinions.

Plaintiffs’ argument that Dr. Kenton failed to consider certain Level I literature noting “episodes” of chronic pain in forming her opinions on the rarity of chronic pain hinges on the fundamental assumption that such Level I literature “draws the opposite conclusion” to the sources on which she does rely. Pltf. Motion, Dkt. 2088, at 11-12. As noted by the Court, “methodology may be unreliable if [the expert] does not explain why certain *contrary* scientific literature was rejected or not considered.” *In re: Ethicon*, 2016 WL 4945099, at *3 (emphasis added). Plaintiffs’ assertion that Dr. Kenton “discounts” contrary data concerning pain is unfounded, however. Dr. Kenton does not opine that TTV devices are *never* associated with chronic pain, rather that such incidents are *rare*. This opinion is not at odds with data showing the existence of “episodes” of chronic pain. Dr. Kenton cannot be expected to preemptively explain why she did not cite or explain away literature which neither supports nor directly contradicts her opinions on chronic pain.

At best, Plaintiffs challenge Dr. Kenton’s testimony as inconsistent or weak compared to their interpretation of the data. These arguments, however, go to the weight of Dr. Kenton’s testimony, not the admissibility, and are not appropriate for Plaintiffs’ Motion. *See Daubert*, 509 U.S. at 596. Dr. Kenton’s opinions, whether or not Plaintiffs agree with them, are based in sound methodology and admissible. Plaintiffs’ Motion to exclude them should be denied.

V. Dr. Kenton Does Not Offer Opinions on the Blaivas Article.

The Plaintiffs also “seek to exclude any testimony that Dr. Kenton may offer at trial regarding a specific article written by Dr. Blaivas.” *In re: Ethicon*, 2016 WL 4945099, at *4. As noted by the Court in its Order, “Dr. Kenton did not cite or otherwise offer an opinion on the article until the plaintiffs’ counsel asked her about it in her deposition” and “the plaintiffs have wholly manufactured this situation.” *Id.* Plaintiffs have adopted their Wave 1 motion and memorandum without modification, and Ethicon has incorporated by reference its Wave 1 Opposition. *See supra* n.1. As nothing has changed with respect to this argument, Ethicon requests that the Court adopt its Wave 1 ruling here and deny Plaintiff’s motion to exclude opinions related to the Blaivas article as moot.

VI. Dr. Kenton Has Not Offered “Contradictory Opinions” and Plaintiffs Fail to State Any Basis for Exclusion of Such Alleged Contradictory Opinions Based on Admissibility.

Finally, Plaintiffs argue that certain parts of Dr. Kenton’s deposition testimony contradict opinions offered in her Report. As previously addressed in its Wave 1 Opposition and contrary to Plaintiffs’ argument, Dr. Kenton’s deposition does not contradict any opinions offered in her Report. Moreover, in its Order the Court addressed numerous “recurring issues” being argued in the MDL *Daubert* motions. *In re: Ethicon*, 2016 WL 4945099, at *4-5. One of these recurring issues is that, like Plaintiffs in their motion on Dr. Kenton, “many of the motions also ask the court to require an expert to offer testimony consistent with that expert’s deposition or report or the like.” *Id.* at *5. As noted by the Court in its Order, this “matter is more appropriately handled via cross-examination or impeachment as appropriate” and the “court will not force an expert to testify one way or another.” *Id.* Again, because Plaintiffs have adopted their Wave 1

argument without modification and Ethicon has incorporated its argument in opposition, Ethicon requests that the Court adopt its Wave 1 ruling here.

CONCLUSION

For the reasons stated above, the Court should deny Plaintiffs' Motion to Exclude the Testimony of Kimberly Kenton, M.D., M.S.

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I, Christy D. Jones, certify that on this date, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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